510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 0 1 2013

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the INFINITY™ Total Ankle System.

1. **Submitted By:** Wright Medical Technology, Inc.
   5677 Airline Road
   Arlington, TN 38002

   Date: April 1, 2013

   Contact Person: Samir Ibrahim, PhD, RAC
   Regulatory Affairs Specialist II
   Phone: (901) 290-5909
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2. **Proprietary Name:** INFINITY™ Total Ankle System

   Common Name: Ankle Prosthesis

   Classification Name and Reference: 21 CFR 888.3110 – Class II

   Device Product Code, Device Panel: HSN: Orthopedic

3. **Predicate Devices:** K051023 – INBONE® Total Ankle System
   K053569 – DePuy Agility™ Total Ankle Prosthesis
   K100886 – INBONE® II Total Ankle System
   K103374 – INBONE® Total Ankle System

4. **Device Description**

   The INFINITY™ Total Ankle System is a fixed-bearing total ankle prosthesis that restores mobility to a failing ankle joint. It encompasses three components (i.e., tibial tray, tibial insert, and talar dome) that are assembled to create a two-piece prosthesis. The device is composed of Titanium Alloy, Cobalt Chrome, Ultra High Molecular Weight Polyethylene, and commercially pure Titanium and each component is available in multiple sizes to accommodate variable patient anatomy.

5. **Intended Use**

   Intended Use: The INFINITY™ Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications for Use: The INFINITY™ Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INFINITY™ Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

6. Technological Characteristics Comparison

The general technological features of the INFINITY™ Total Ankle System are similar to the predicate devices with regard to design and materials. The goal of the INFINITY™ design was to limit the amount of bone resection and soft tissue dissection required for ankle arthroplasty; hence, the overall profile of the INFINITY™ Total Ankle was significantly reduced relative to the INBONE® II predicate.

7. Substantial Equivalence – Non-Clinical Evidence

The following non-clinical analysis was performed:

1. Bone interface stability testing
2. Component stability testing
3. Fatigue testing
4. Contact area / contact stress testing

The results of this analysis show that the subject INFINITY™ Total Ankle System can be expected to perform at least as well as the legally marketed predicates referenced above. The safety and effectiveness of the INFINITY™ Total Ankle System is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within this 510k submission.

8. Substantial Equivalence – Clinical Evidence

N/A

9. Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Incorporated
% Samir Ibrahim, Ph.D.
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Letter dated: April 1, 2013

Re: K123954
Trade/Device Name: INFINITY™ Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: March 18, 2013
Received: March 19, 2013

Dear Dr. Ibrahim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K123954

Device Name: INFINITY™ Total Ankle System

Indications For Use:

The INFINITY™ Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INFINITY ™ Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number _____

Prescription Use __√__ (Per21 CFR 801.109)

OR

Over-The Counter Use ____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices